APPROVED
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Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel

RAZOBIN P1536410

RAZOBIN P1536410

PROFESSION INFORMATION

SCHEDULING STATUS

SOUTH AFRICA: S4

NAMIBIA: NS2

PROPRIETARY NAME (and dosage form):
RAZOBIN 2 (Lyophilised powder for solution for injection/infusion)
RAZOBIN 3 (Lyophilised powder for solution for injection/infusion)
RAZOBIN 4 (Lyophilised powder for solution for injection/infusion)

COMPOSITION:
RAZOBIN 2
Each vial contains piperacillin sodium and tazobactam sodium cryodessicated powder for solution for injection/infusion equivalent to piperacillin 2,0 g and tazobactam 0,25 g. Each vial contains 4,7 milli-equivalents (108 mg) of sodium.

RAZOBIN 3
Each vial contains piperacillin sodium and tazobactam sodium cryodessicated powder for solution for injection/infusion equivalent to piperacillin 3,0 g and tazobactam 0,375 g. Each vial contains 7,05 milli-equivalents (162 mg) of sodium.

RAZOBIN 4
Each vial contains piperacillin sodium and tazobactam sodium cryodessicated powder for solution for injection/infusion equivalent to piperacillin 4,0 g and tazobactam 0,5 g. Each vial contains 9,40 milli-equivalents (216 mg) of sodium.

PHARMACOLOGICAL CLASSIFICATION:
A 20.1.1 Broad and medium spectrum antibiotics

PHARMACOLOGICAL ACTION:
Pharmacodynamics
Piperacillin is a broad spectrum, semi-synthetic penicillin. It is active against many gram-positive and gram-negative aerobic and anaerobic bacteria, and exerts bactericidal activity by inhibition of both septum and cell wall synthesis. Tazobactam, a triazolylmethyl penicillanic acid sulfone, is an inhibitor of many β-lactamases, including the plasmid and chromosomally mediated enzymes. The antibiotic spectrum of piperacillin is enhanced and extended by the presence of tazobactam in the piperacillin/tazobactam formulation.
A wide range of gram-positive and gram-negative organisms are susceptible to **RAZOBIN**.
The following are resistant:

- Piperacillin-tazobactam-resistant *Pseudomonas aeruginosa*
- Incidence of cross-resistance with other antipseudomonal penicillins
- All methicillin-resistant staphylococci

Pharmacokinetics
Absorption: Peak plasma concentrations of piperacillin and tazobactam are attained immediately after completion of an intravenous infusion of **RAZOBIN**.

Metabolism: Piperacillin is metabolised to a minor microbiologically active desethyl metabolite. Tazobactam is metabolised to a single metabolite that lacks pharmacological and antibacterial activities.

Excretion: Both piperacillin and tazobactam are eliminated via the kidney by glomerular filtration and tubular secretion. Piperacillin is excreted rapidly as unchanged substance, with 68 % of the administered dose excreted in the urine. Tazobactam and its metabolite are eliminated primarily by renal excretion with 80 % of the administered dose excreted as unchanged substance and the remainder as the single metabolite. Piperacillin, tazobactam and desethyl piperacillin are also secreted into the bile.

Plasma protein binding: Both piperacillin and tazobactam are approximately 30 % bound to plasma proteins. The protein binding of either piperacillin or tazobactam is unaffected by the presence of the other compound. Protein binding of the tazobactam metabolite is negligible.

Distribution: Piperacillin and tazobactam are widely distributed into tissues and body fluids including intestinal mucosa, gall bladder, lung, female reproductive tissues (uterus, ovary, and fallopian tubes), interstitial fluid, and bile. Mean tissue concentrations are generally 50 % to 100 % of those in plasma. Distribution of piperacillin and tazobactam into cerebrospinal fluid is low in subjects with non-inflamed meninges.

Special Populations:
Patients with renal insufficiency: After the administration of single doses of piperacillin/tazobactam to subjects with renal impairment, the half-life of piperacillin and of tazobactam increases with decreasing creatinine clearance. The increase in half-life is two-fold and four-fold for piperacillin and tazobactam, respectively at creatinine clearance below 20 mL/min compared to patients with normal renal function. Dosage adjustments for piperacillin and tazobactam are recommended in patients where creatinine clearance is below 40 mL/min receiving the usual recommended daily dose of piperacillin and tazobactam (See **"DOSAGE AND DIRECTIONS FOR USE"**).

Patients with hepatic insufficiency: The half-life of piperacillin and of tazobactam increases by approximately 25 % and 18 %, respectively, in patients with hepatic cirrhosis compared to healthy patients.

INDICATIONS:
RAZOBIN is indicated for the treatment of the following systemic and/or local bacterial infections in which susceptible organisms have been detected or are suspected:

Adults:

1. Community acquired pneumonia due to *Haemophilus influenzae*.
2. Intra-abdominal infections caused by piperacillin-resistant beta-lactamase-producing strains of *Escherichia coli* and *Bacteroides fragilis*.
3. Skin and skin structure infections caused by piperacillin-resistant beta-lactamase-producing strains of *Staphylococcus aureus*.
4. In neutropenic patients, **RAZOBIN** plus an aminoglycoside is indicated for bacterial infections.
5. Gynaecological infections including endometritis caused by piperacillin-resistant beta-lactamase-producing strains of *E. coli*.

Children:
CHILDREN UNDER THE AGE OF 12 YEARS:
In neutropenic patients, **RAZOBIN** plus an aminoglycoside is indicated for bacterial infections.

CHILDREN 2-12 YEARS:
RAZOBIN is indicated for the treatment of serious intra-abdominal infections, caused by *E.coli* or Bacteroides species, in hospitalised children aged 2 - 12 years. For paediatric patients below the age of 2 years, **RAZOBIN** has not been evaluated in this indication.

CONTRA-INDICATIONS:
RAZOBIN is contra-indicated in patients with a history of allergic reactions to any of the penicillins and/or cephalosporins or β-lactamase inhibitors or any of the constituents of **RAZOBIN**.
Safety in pregnancy and lactation has not been established (see **"PREGNANCY AND LACTATION"**).

WARNINGS AND SPECIAL PRECAUTIONS:
Serious and occasionally fatal hypersensitivity reactions (anaphylactic/anaphylactoid including shock) have been reported in patients receiving therapy with penicillins. These reactions are more apt to occur in persons with a history of penicillin hypersensitivity or a sensitivity to multiple allergens. There have been reports of patients with a history of penicillin hypersensitivity who have experienced severe hypersensitivity reactions when treated with a cephalosporin. Careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, and other allergens, before initiating therapy with **RAZOBIN**.
If an allergic reaction occurs during therapy with **RAZOBIN**, the antibiotic should be discontinued. Serious hypersensitivity reactions require immediate emergency measures, with epinephrine (adrenaline), corticosteroids and antihistamines. An open airway must be maintained.
Pseudomembranous colitis has been reported. Antibiotic-induced pseudomembranous colitis may occur manifesting as symptoms of severe, persistent diarrhoea which may be life-threatening. The onset of pseudomembranous colitis may occur during or after antibacterial treatment. Therefore, in patients who present with diarrhoea subsequent to the administration of antibacterial agents, it is important to consider this diagnosis. After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to **RAZOBIN** discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes; protein supplementation and treatment with an oral antibacterial medicine effective against *Clostridium difficile*.
Periodic assessment of organ system functions including renal and hepatic functions during prolonged therapy is advisable. Leucopenia and neutropenia may occur, especially during prolonged therapy. Therefore, periodic assessment of haematopoietic function should be performed. In some patients receiving β-lactam antibiotics, bleeding manifestations have occurred. These reactions have sometimes been associated with abnormalities of coagulation tests such as clotting time, platelet aggregation and prothrombin time and are more likely to occur in patients with renal failure. **RAZOBIN** should be discontinued and appropriate therapy instituted if bleeding manifestations occur.
The possibility of the emergence of resistant organisms, which may cause superinfections, should be kept in mind, particularly during prolonged treatment. If this occurs, appropriate measures should be taken. As with other penicillins, if higher than recommended doses are given intravenously, patients may experience convulsions or neuromuscular excitability. This product contains 2,35 mEq (54 mg) of sodium per gram of piperacillin which may influence a patient's overall sodium intake. In patients with low potassium reserves, periodic electrolyte determinations should be made and the possibility of hypokalaemia should be kept in mind with patients who have potentially low potassium reserves and who are receiving diuretic or cytotoxic therapy. Modest elevation of indices of liver function may be observed.
In patients with renal insufficiency or haemodialysis patients, the intravenous dose should be adjusted to the degree of renal function impairment. Patients over 65 years are not at an increased risk of developing adverse effects solely because of age. However, dosage should be adjusted in the presence of renal insufficiency.

Haemophagocytic lymphohistiocytosis (haemophagocytic syndrome):
Haemophagocytic lymphohistiocytosis may occur. Patients should be carefully monitored, and if any abnormalities such as pyrexia, rash, neurological symptoms, splenomegaly, swollen lymph nodes, cytopenia, increased LDH, hyperfertrinaemia, hypertriglyceridaemia, hepatic impairment, or coagulation abnormalities are observed, administration of **RAZOBIN** should be discontinued, and appropriate measures should be taken.

Effects on ability to drive and use machines:
There is no information to show that **RAZOBIN** affects the ability to drive a car or operate machinery.

INTERACTIONS:
Interactions with other medicines:
No interaction is found between **RAZOBIN** and vancomycin.
Concurrent administration of probenecid and **RAZOBIN** produced a lower renal clearance and a longer half-life for both piperacillin and tazobactam; however, peak plasma concentrations of either medicine is unaffected.
The pharmacokinetics of tobramycin in subjects with normal renal function and with mild or moderate renal impairment was not significantly altered by piperacillin either alone or with tazobactam. The pharmacokinetics of piperacillin, tazobactam, and the M1 metabolite were also not significantly altered by tobramycin administration.
Whenever **RAZOBIN** is used concurrently with another antibiotic, especially an aminoglycoside, the medicines must not be mixed in intravenous solutions or administered concurrently due to physical incompatibility.
During simultaneous administration of high doses of heparin, oral anticoagulants and other medicines that may affect the blood coagulation system and/or the thrombocyte function, the coagulation parameters should be monitored regularly and tested more frequently. Piperacillin has been implicated in the prolongation of the neuromuscular blockage of vecuronium, when given concomitantly with vecuronium. Due to their similar mechanism of action, it is expected that the neuromuscular blockade produced by any of the non-depolarising muscle relaxants could be prolonged in the presence of piperacillin.
Since piperacillin may reduce the excretion of methotrexate, the serum levels of methotrexate should be monitored in patients to avoid medicine toxicity.

Pharmaceutical Incompatibilities:
RAZOBIN should not be mixed with other medicines in an infusion bottle or syringe since compatibility has not been established. Whenever **RAZOBIN** is used concurrently with another antibiotic (e.g. aminoglycosides), the medicines must be administered separately. The mixing of **RAZOBIN** with an aminoglycoside *in vitro* can result in the aminoglycoside being substantially inactivated.
RAZOBIN should not be mixed with solutions containing only sodium bicarbonate, because of chemical instability.
Lactated Ringer's solution is not compatible with **RAZOBIN**.
RAZOBIN should not be added to albumin hydrolysates or blood products.

Laboratory Tests:
There have been reports of positive test results using the Bio-Rad Laboratories Platelia Aspergillus EIA test in patients receiving **RAZOBIN** injection who were subsequently found to be free of Aspergillus infection. Cross-reactions with non-Aspergillus polysaccharides and polyfuranoses with Bio-Rad Laboratories Platelia Aspergillus EIA test have been reported. Therefore, positive test results in patients receiving **RAZOBIN** should be interpreted cautiously and confirmed by other diagnostic methods. The administration of **RAZOBIN** may result in a false-positive reaction for glucose in the urine using a copper-reduction method. Therefore, it is recommended that glucose tests based on enzymatic glucose oxidase reactions should be used.

PREGNANCY AND LACTATION:
Safety in pregnancy and lactation has not been established.
Adequate studies on the use of **RAZOBIN** during pregnancy and the period of breastfeeding are not available. **RAZOBIN** did not affect fertility in rats and was not teratogenic in rats or mice. Piperacillin and tazobactam cross the placenta. Piperacillin is excreted in low concentrations in human milk. Tazobactam concentrations in human milk have not been studied.

DOSAGE AND DIRECTIONS FOR USE:
RAZOBIN may be given by slow intravenous infusion over a 30 minute period.

Adults and children 12 years and older:
The usual dosage for adults and juveniles with normal renal function is 4/0,5 g piperacillin/tazobactam given every eight hours.
The dosage in immunocompromised and neutropenic patients with infection is 4/0,5 g piperacillin/tazobactam every 6 hours in combination with an aminoglycoside.

Children under the age of 12 years:
RAZOBIN is only recommended for the treatment of children with neutropenia.
For children weighing over 50 kg, follow the adult dosing guidance, including the aminoglycoside.
For children with normal renal function and weighing less than 50 kg, the dose should be adjusted to 90 mg/kg (80 mg piperacillin/10 mg tazobactam) administered every 6 hours, in combination with an aminoglycoside.

Renal Insufficiency:
In patients with renal insufficiency, the intravenous dose should be adjusted to the degree of actual renal function impairment. The suggested daily doses are as follows:

INTRAVENOUS DOSAGE SCHEDULE FOR ADULTS WITH IMPAIRED RENAL FUNCTION	
Creatinine Clearance (mL/min)	**Recommended Piperacillin/Tazobactam Dosage**
90 - 40	12 g/1,5 g/day in divided doses of 4 g/0,5 g every 8 hours or 3 g/0,375 g every 6 hours
20 - 40	8 g/1,0 g/day in divided doses of 2 g/0,25 g every 6 hours
< 20	6 g/0,75 g/day in divided doses of 2 g/0,25 g every 8 hours

For patients on haemodialysis, the maximum daily dose is 2 g/0,25 g of piperacillin/tazobactam every 8 hours. In addition, because haemodialysis removes 30 % - 40 % of piperacillin in 4 hours, one additional dose of 0,75 g piperacillin/ tazobactam should be administered following each dialysis period. For patients with renal failure and hepatic insufficiency, measurement of serum levels of piperacillin/ tazobactam will provide additional guidance for adjusting dosage.

Neutropenic patients:
In treating neutropenic patients, full therapeutic doses of **RAZOBIN** and an aminoglycoside should be used. The possibility of hypokalaemia should be kept in mind in patients who have low potassium reserves, and periodic electrolyte determinations should be made in these patients.

✂ ▼DETACH BEFORE DISPENSING ✂

PASIËNTINLIGTINGSBLAD

SUID-AFRIKA: S4

NAMIBIË: NS2

RAZOBIN 2 (Gelioflisseerde poeier vir oplossing vir inspuiting/infusie)
RAZOBIN 3 (Gelioflisseerde poeier vir oplossing vir inspuiting/infusie)
RAZOBIN 4 (Gelioflisseerde poeier vir oplossing vir inspuiting/infusie)
Piperasillien-natrium/ Tasobaktaam-natrium

Lees hierdie hele brosjure versigtig voordat RAZOBIN aan jou toegedien word.
- Hou hierdie brosjure. Jy mag dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter of jou apteker.
- **RAZOBIN** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense te deel nie. Dit mag hulle skade aandoen, ookal het hulle dieselfde simptome as u.

1. WAT RAZOBIN BEVAT
Die aktiewe stowwe is piperasillien-natrium en tasobaktaam-natrium.
RAZOBIN 2:
Elke fiesie bevat piperasillien-natrium en tasobaktaam-natrium kriogedroogde poeier vir oplossing vir inspuiting/infusie ekwivalent aan piperasillien 2,0 g en tasobaktaam 0,25 g.
Elke fiessie bevat 4,7 milli-ekwivalente (108 mg) natrium.
RAZOBIN 3:
Elke fiesie bevat piperasillien-natrium en tasobaktaam-natrium kriogedroogde poeier vir oplossing vir inspuiting/infusie ekwivalent aan piperasillien 3,0 g en tasobaktaam 0,375 g.
Elke fiessie bevat 7,05 milli-ekwivalente (162 mg) natrium.
RAZOBIN 4:
Elke fiessie bevat piperasillien-natrium en tasobaktaam-natrium kriogedroogde poeier vir oplossing vir inspuiting/infusie ekwivalent aan piperasillien 4,0 g en tasobaktaam 0,5 g.
Elke fiessie bevat 9,40 milli-ekwivalente (216 mg) natrium.

2. WAARVOOR RAZOBIN GEBRUIK WORD
RAZOBIN inspuiting bevat twee aktiewe bestanddele, piperasillien, wat 'n penisillien-tipe antibiotikum is, en tasobaktaam, wat 'n medisyne is wat verhoed dat bakteriële piperasillien inaktiveer.
RAZOBIN word gebruik om bakteriële infeksies soos dié wat jou bors, buik, en vel affekteer en ginekologiese infeksies, te behandel.
RAZOBIN mag ook gebruik word saam met medisyne wat as "aminoglikosiede" bekend is om infeksies te behandel by pasiënte wat nie in staat is om op normale wyse infeksies te bekamp nie.
RAZOBIN word gebruik om bakteriële infeksies te behandel by kinders onder die ouderdom van 12 jaar met lae witbloedseltellings (neutropenie), wat dus 'n verminderde vermoë het om infeksie te bekamp (dit word gebruik in kombinasie met 'n aminoglikosied-antibiotikum vir hierdie doel).
By gehospitaliseerde kinders tussen die ouderdomme van 2 tot 12 jaar, word **RAZOBIN** gebruik om ernstige infeksies wat die buik te behandel. **RAZOBIN** word nie vir die behandeling van abdominale infeksies by kinders onder die ouderdom van 2 jaar, aanbeveel nie.

3. VOORDAT JY RAZOBIN ONTVANG
Jy behoort RAZOBIN nie te ontvang nie:
- Indien jy ooit 'n ongewone of allergiese reaksie gehad het op **RAZOBIN**, antibiotika wat as penisilliene of sefalosporiene bekend staan, of teen medisyne wat beta-laktamase-inhibeerders genoem word.
- Indien jy swanger is of borsvoed.

Neem spesiale sorg met RAZOBIN
Voordat jy **RAZOBIN** ontvang:
- Vertel jou dokter indien jy allergies is vir penisilliene, sefalosporiene, of enige ander medikasies, of 'n geskiedenis van allergie het. Staak inname van **RAZOBIN** en kry noodhulp indien jy enige van hierdie tekens van 'n ernstige allergiese reaksie ontwikkel: probleme met asemhaling; swelling van jou gesig, lippe, tong of keel.
- Vertel jou dokter indien jy diarree tydens of na die inname van **RAZOBIN** ontwikkel. Indien dit ernstig of aanhoudend word, of bloed of slym bevat, behoort jy dadelik jou dokter daarvan te vertel. Dit mag 'n teken van 'n ernstige newe effek wees wat die derm affekteer. Jy het moontlik dringende mediese sorg nodig.
- Tydens langtermyn behandeling, sal jou dokter moontlik roetine bloedtoetse wil doen om jou nierfunksie, lewerfunksie en die vlak van bloedselle te monitor.
- Vertel jou dokter dadelik indien jy bewus word daarvan dat jy maklikker bloei of kneus as normaal.
- Vertel jou dokter indien jy simptome van 'n nuwe infeksie ontwikkel.
- Indien jy dosisse ontvang wat hoër is as dié wat aanbeveel word, mag jy aanvalle (konvulsies) ondervind.
- Vertel jou dokter as jy op 'n lae natrium (sout) dieet is - **RAZOBIN** bevat natrium.
- Vertel jou dokter as jy lae vlakke van kalium in jou bloed het of as jy diuretika (vir hartprobleme of hoë bloeddruk) of medisyne vir kanker neem. Jou dokter sal moontlik van tyd tot tyd 'n bloedmonster neem om die vlakke van kalium in jou bloed te toets.
- Vertel jou dokter as jy nierprobleme het, of as jy hemodialisebehandeling ontvang. Jou dokter mag vasstel hoe goed jou niere werk voordat hy hierdie medisyne vir jou gee en die dosis vir jou aanpas.
- **RAZOBIN** mag inmeng met sekere laboratoriumtoetse. Maak seker dat jou dokter en die laboratoriumpersoneel weet dat jy **RAZOBIN** gebruik.
- **RAZOBIN** kan sommige toetse vir glukose in die urien beïnvloed. Penisilliene wat in die urien uitgeskei word, kan 'n vals-positiewe resultaat veroorsaak. Die dokter sal 'n toets aanvra wat nie deur penisilliene beïnvloed word nie.

Hemofagositiese limfohistiositose (hemofagositiese sindroom):
Hemofagositiese limfohistiositose kan voorkom. Vertel jou dokter as enige abnormaliteite soos koors, geswelde kliere, swak gevoel, lighoofdigheid, kortasem, kneusing of veluitslag waargeneem word. Toediening van **RAZOBIN** moet gestaak word en toepaslike maatreëls moet getref word.

Swangerskap en Borsvoeding:
Vertel jou dokter indien jy swanger is, beplan om swanger te word, of jou baba borsvoed.
- Die veiligheid van **RAZOBIN** tydens swangerskap en borsvoeding is nie vasgestel nie.

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander gesondheidsbeampte vir advies nader voordat u **RAZOBIN** ontvang.

Bestuur en gebruik van masjiene:
Daar is geen inligting beskikbaar wat aandui dat **RAZOBIN** die vermoë om te bestuur of masjinerie gebruik, affekteer nie.

Neem van ander medisyne saam met RAZOBIN :

Vertel altyd jou gesondheidsorgdeskundige indien jy enige ander medisyne neem.
(Dit sluit komplementêre of tradisionele medisyne in).

- Medisyne vir jig (probenesied).
- Tobramisien, 'n antibiotikum.
- Aminoglikosied-antibiotika.
- Preparate om die bloed te verdun (bv. warfarien, heparien) - jou dokter sal moontlik die stollingstyd van jou bloed meer dikwels wil moniteer indien jy antikoagulant-behandeling in kombinasie met **RAZOBIN** ontvang.
- Metotreksaat wat gebruik word om kanker, rumatoïede artritis en ander inflammatoriese toestande te behandel - Piperasillien mag die verwydering van metotreksaat uit die ligaam verminder wat die risiko van newe-effekte kan verhoog. Jou dokter sal moontlik die hoeveelheid metotreksaat in jou bloed wil monitor terwyl jy behandeling met metotreksaat in kombinasie met hierdie medisyne ontvang.
- Vekuronium, 'n spierverslapper wat in chirurgie gebruik word.

Indien jy enigeen van hierdie medisyne gebruik, sal jy moontlik **RAZOBIN** nie kan neem nie, of jy sal dalk dosisaanpassings benodig, of jou dokter sal jou moontlik versigtig vir newe effekte moet monitor.

4. HOE OM RAZOBIN TE ONTVANG
- 'n Dokter of verpleegster in 'n hospitaal sal vir jou **RAZOBIN** gee. Dit sal gewoonlik as 'n stadige inspuiting in 'n bloedvat oor 30 minute vir jou gegee word.
- Die gebruikliike dosis **RAZOBIN** vir volwassenes en jeugdiges is 4/0,5 g wat elke 8 uur toegedien word.
- Kinders met infeksies in of naby die buik:
- Hoe lank **RAZOBIN** vir jou gegee sal word, is afhanklik van die tipe en erns van jou infeksie. Dit behoort vir ten minste vyf dae gegee te word, en vir 48 uur nadat alle tekens van siekte en koors verdwyn het.
- Indien jy nierprobleme het, sal jou dokter moontlik die dosis **RAZOBIN** moet aanpas, asook hoe dikwels dit gegee word.

Indien jy oorder die indruk verkeer dat die effek van **RAZOBIN** te sterk of te swak is, gesels met jou dokter daaroor.

Indien jy meer RAZOBIN ontvang as wat jy behoort te kry:
Omdat 'n gesondheidsorgdeskundige **RAZOBIN** sal toedien, sal hy/sy die dosis beheer. In 'n geval van oordosering sal jou dokter dit oordosis hanteer. Simptome van oordosis mag naarheid, braking, diarree of aanvalle (konvulsies) insluit.

Indien jy 'n dosis RAZOBIN oorslaan:
Jou mediksie sal gewoonlik vir jou deur 'n gesondheidsorgdeskundige gegee word.
Indien jy van mening is dat 'n dosis moontlik oorgeslaan is, moet jy asseblief jou dokter of verpleegster daarvan vertel.

5. MOONTLIKE NEWE EFFEKTE
RAZOBIN kan newe effekte veroorsaak.
Kry mediese noodhulp indien jy enige van hierdie tekens van 'n allergiese reaksie ontwikkel:
- Galbulte; probleme met asemhaling; swelling van jou gesig, lippe, tong, of keel.

Skakel jou dokter dadelik indien jy enige van hierdie ernstige newe effekte ondervind:
- Diarree wat waterig of bloedig is.
- Maklike kneusing of bloeding, neusbloeding.
- Wydverspreide rooiheid van die vel, of ernstige afskilfering van die vel.
- Aanvalle (konvulsies).
- Koors, koukoors, seer keel, of ander tekens van infeksie.
- Bloedarmoede (hoogheid, kortasem en bleek voorkoms).
- Inflammasie van die wand van 'n bloedvat en 'n bloedklont wat in die aangetaste deel van die bloedvat vorm (pyn in die deel van die ligogaam wat aangetas word, rooiheid van die vel, swelling van die ligsaamsdeel wat aangetas is, warmte en teerheid oor die bloedvat).

Vertel jou dokter as jy bewus word van enige van die volgende newe effekte en as dit jou bekommer of indien enige van hierdie simptome ernstig is of nie verdwyn nie:
- Sproei, hoofpyn, probleme met slaap, spierpyn en -swakheid, hallusinasies, droë mond, pyn, swelling, warmte of rooiheid rondom die inspuitingsplek, bloeding, naarheid (misikheid, gevoel dat mens gaan opgooi), diarree, braking, hardwywigheid, indigestie, inflammasie van die mond, abdominale pyn, veluitslag, eksseem, jeuk, galbulte, gewrigspyn, toename in sweet, koors, moegheid; swelling as gevolg van vloeistofretensie; vermoeidheid en swerteng.
- Ongewenste effekte van **RAZOBIN** waarvan jy dalk nie bewus sal wees nie terwyl jy jou medisyne ontvang, sluit in lae bloedtruk (wat as duiseligheid manifesteer wanneer jy staan), inflammasie van die bloedvate (swelling of rooiheid oor die lengte van 'n bloedvat wat uiters teer voel indien daaraan geraak word), veranderings in die getal rooi- of witbloedselle of plaatjies, of die vlakke van kalium, glukose of proteïen in jou bloed, verhogings in lewerensiem- of bilirubienvlakke in die bloed, veranderings in lewerfunksie (wat vergeling van die wit deel van jou oë of vel, jeukerige vel, donkerder urien en ligter stoelgang veroorsaak), veranderings in nierfunksie.

Nie alle newe effekte wat vir **RAZOBIN** aangemeld is, word in hierdie brosjure ingesluit nie. Indien jou algemene gesondheid sou vererger terwyl jy **RAZOBIN** ontvang, moet jy asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies raadpleeg.

6. BERGING EN WEGDOENING VAN RAZOBIN
Droë poeier: Flessies wat steriele **RAZOBIN** droë poeier bevat, mag by beweerde kamertemperatuur (teen of onder 25 °C) bewaar word. Hou die flessie in die buitenste karton totdat dit gebruik gaan word.
Oplossings: Die flessies wat die hersaamgestelde oplossing bevat, behoort dadelik gebruik te word of teen 2 - 8 °C vir nie langer as 24 uur bewaar te word nie.
Chemiese en fisiese in-gebruikstabiliteit is vir 24 uur teen 25 °C en 48 uur teen 2 - 8 °C aangetoon. **RAZOBIN** bevat geen preserveermiddels nie en herkonstitusie/verdunning behoort daarom in gekontroleerde en gevalideerde aseptiese kondisies plaas te vind.
RAZOBIN is slegs vir eenmalige gebruik bedoel. Enige ongebruikte porsie van die hersaamgestelde/ verdunde oplossing moet weggedoen (weggegooi) word.
RAZOBIN word gewoonlik gestoor en gehanteer deur 'n gesondheidsorgverskaffer. Indien jy **RAZOBIN** by die huis gebruik, moet jy **RAZOBIN** bewaar volgens die instruksies van jou apteker of gesondheidsorgdeskundige.
Bewaar alle medisyne buite bereik en sig van kinders.

7. AANBIEDING VAN RAZOBIN
RAZOBIN 2:
30 mL helder, kleurlose, buisvormige glasflessies wat met 20 mm gryskleurige broombutiel rubberproppe voorsien is en met 20 mm violet-gekleurde PP skuif.
RAZOBIN 3:
30 mL helder, kleurlose, buisvormige glasflessies wat met 20 mm gryskleurige broombutiel rubberproppe voorsien is en met 20 mm ligte blou-gekleurde PP skuif.
RAZOBIN 4:
48 mL helder, kleurlose, buisvormige glasflessies wat met 20 mm gryskleurige broombutiel rubberproppe voorsien is en met 20 mm rooi-gekleurde PP skuif.
Verpakkingsgrootte: 1. 'n Enkel flessie in 'n vouafgedrukte kartondosie met 'n voubiljet.
2. 10 flessies verpak in n ongedrukte E-gegroefde boks met afskorting en 'n voubiljet

8. IDENTIFIKASIE VAN RAZOBIN
'n Wit tot naaswit kriogedroogde poeier. Wanneer dit hersaamgestel is, word 'n ligte geelkleurige, helder oplossing vry van sigbare deeltjies gevorm.

9. REGISTRASIENOMMER/ VERWYSINGSNOMMER
SUID-AFRIKA:
RAZOBIN 2: 44/20.1.1/0080
RAZOBIN 3: 44/20.1.1/0081
RAZOBIN 4: 44/20.1.1/0082
NAMIBIË:
RAZOBIN 2: 17/20.1.1/0039
RAZOBIN 3: 17/20.1.1/0040
RAZOBIN 4: 17/20.1.1/0041

10. NAAM EN ADRES VAN REGISTRASIEHOUER
Aurogen South Africa (Edms) Bpk.
Woodhill Kantoorpark, Gebou Nr. 1, Eerste Vloer,
Phillip Engelbrechtlaan 53,
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Suid-Afrika.

11. DATUM VAN PUBLIKASIE
Datum van registrasie:
6 Junie 2014
Datum van hersiening:
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Black A/s: 280 x 660 mm

eugia Packaging Development		Product Name: RAZOBIN	Component: Leaflet	Item Code: P1536410	Date & Time: 19.02.2024 & 6.20 PM
		Customer / Country: South_Africa_Unit-12	Version No.: 02	Reason Of Issue: Revision	Reviewed / Approved by
Team Leader: Sivakumar		Dimensions: 280 x 660 mm	No. of Colours : 01		
Initiator: Jitender					
Artist: Vision Graphic Designers		Pharmacode: 36410			Sign / Date
Additional Information : Supersede Item Code: P1535376					

Duration of therapy:
In acute infections, treatment with **RAZOBIN** should be for a minimum of 5 days and continued for 48 hours beyond resolution of clinical symptoms or the fever.
The usual duration of treatment is 7 - 10 days.

Hospitalised children with intra-abdominal infection:
For children aged 2 to 12 years, weighing up to 40 kg, and with normal renal function, the recommended dosage is 112,5 mg/kg (100 mg piperacillin / 12,5 mg tazobactam) every 8 hours.
For children aged 2 to 12 years, weighing over 40 kg, and with normal renal function, follow the adult dose guidance, i.e. 4,5 g (4 g piperacillin / 0,5 g tazobactam) every 8 hours.
The duration of therapy should be guided by the severity of the infection and the patient's clinical and bacteriological progress. Therapy is recommended to be a minimum of 5 days and a maximum of 14 days, considering the dose administration should continue at least 48 hours after the resolution of clinical signs and symptoms.

Children aged 2 —years with renal insufficiency:
The pharmacokinetics of **RAZOBIN** have not been studied in paediatric patients with renal impairment. The following dosage adjustment for paediatric patients aged 2 - 12 years with renal impairment is recommended.

INTRAVENOUS DOSAGE SCHEDULE FOR CHILDREN AGED 2 – 12 YEARS WITH IMPAIRED RENAL FUNCTION

Creatinine Clearance (mL/min)	Recommended Piperacillin/Tazobactam Dosage
> 50	112,5 mg/kg (100 mg/12,5 mg) every 8 hours
≤ 50	78,75 mg/kg (70 mg/8,75 mg) every 8 hours

The dosage modification is only an approximation. Each patient must be monitored closely for signs of medicine toxicity. Medicine dose and interval should be adjusted accordingly.

Reconstitution Directions:
***Diluents for Reconstitution:* (See "INTERACTIONS: Pharmaceutical Incompatibilities")**
Sterile Water for Injection.
Sodium Chloride Injection.
Each vial of 2 g/ 0,25 g **RAZOBIN** should be reconstituted with at least 10 mL of one of the above diluents. Shake until dissolved.
Each vial of 3 g/0,375 g **RAZOBIN** should be reconstituted with at least 15 mL of one of the above diluents. Shake until dissolved.
Each vial of 4 g/0,5 g **RAZOBIN** should be reconstituted with at least 20 mL of one of the above diluents. Shake until dissolved.

For intravenous infusion:
The reconstituted solution may be further diluted to the desired volume (e.g. 50 mL - 150 mL) with one of the reconstitution diluents or with dextrose 5 % in water.

SIDE EFFECTS:
Infections and infestations:
Less frequent: Candidal superinfections

Blood and the lymphatic system disorders:
Less frequent: Leukopenia, neutropenia, thrombocytopenia, anaemia, bleeding manifestations (including purpura, epistaxis, bleeding time prolonged), eosinophilia, haemolytic anaemia, agranulocytosis, Coombs direct test positive, pancytopenia, prolonged partial thromboplastin time, prothrombin time prolonged, thrombocytosis

Immune system disorders:
Less frequent: Hypersensitivity reaction, anaphylactic/anaphylactoid reaction (including shock)

Metabolism and nutrition disorders:
Less frequent: Hypoalbuminaemia, hypoglycaemia, hypoproteinaemia, hypokalaemia

Psychiatric disorders:
Less frequent: Hallucinations, confusion, depression

Nervous system disorders:
Less frequent: Headache, insomnia, muscular weakness, convulsion, dry mouth

Cardiac disorders:
Less frequent: Tachycardia, including supraventricular and ventricular, bradycardia, dysrhythmia, including atrial fibrillation, ventricular fibrillation, cardiac arrest, cardiac failure, circulatory failure, myocardial infarction

Vascular disorders:
Less frequent: Hypotension, phlebitis, thrombophlebitis, flushing

Gastrointestinal disorders:
Frequent: Diarrhoea, nausea, vomiting
Less frequent: Constipation, dyspepsia, jaundice, stomatitis, abdominal pain, pseudomembranous colitis

Hepato-biliary disorders:
Less frequent: Increased alanine aminotransferase, increased aspartate aminotransferase, increased bilirubin, increased blood alkaline phosphatase, increased gamma-glutamyltransferase, hepatitis

Skin and subcutaneous tissue disorders:
Frequent: Rash
Less frequent: Pruritus, urticaria, erythema, bullous dermatitis, erythema multiforme, increased sweating, eczema, exanthema, Stevens-Johnson Syndrome, toxic epidermal necrolysis

Musculoskeletal, connective tissue and bone disorders:
Less frequent: Arthralgia, myalgia

Renal and urinary disorders:
Less frequent: Increased blood creatinine, dysuria, urinary retention, interstitial nephritis, renal failure, increased blood urea

General disorders and administrative site conditions:
Less frequent: Fever, injection site reaction, rigors, tiredness, oedema
Piperacillin therapy has been associated with an increased incidence of fever and rash in cystic fibrosis patients.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
(See "**SIDE EFFECTS**".) The majority of events experienced during overdosage include nausea, vomiting and diarrhoea which also occurs with the usual recommended dosages. If higher than recommended doses are given intravenously, particularly in the presence of renal failure, patients may experience neuromuscular excitability or convulsions.
Treatment should be supportive and symptomatic according to the patient's clinical presentation. There is no known specific antidote. Excessive serum concentrations of either piperacillin or tazobactam may be reduced by haemodialysis. In the event of an emergency, all required intensive medical measures are indicated as in the case of piperacillin. In case of motor excitability or convulsions, anticonvulsive agents (e.g. diazepam or barbiturates) may be indicated. In case of severe, hyperallergic (anaphylactic) reactions, the usual countermeasures are to be initiated (antihistamines, corticosteroids, sympathicomimetic medicines and, if required, oxygen and airway management). The possibility of antibiotic-induced life-threatening pseudomembranous colitis must be taken into consideration in case of severe, persistent diarrhoea.
Therefore, **RAZOBIN** must be discontinued immediately in such cases and suitable therapy be initiated (e.g. oral teicoplanin or oral vancomycin). Preparations, which inhibit peristalsis, are contraindicated.

IDENTIFICATION:
A white to off-white cryodessicated powder. When reconstituted, a light yellow coloured, clear solution, free from visible particulate matter is formed.

PRESENTATION:
RAZOBIN 2
30 mL clear, colourless, tubular glass vials fitted with 20 mm grey colour bromo butyl rubber stoppers and sealed with 20 mm aluminium seal with a violet coloured PP disc.
RAZOBIN 3
30 mL clear, colourless, tubular glass vials fitted with 20 mm grey colour bromo butyl rubber stoppers and sealed with 20 mm aluminium seal with a light blue coloured PP disc.
RAZOBIN 4
48 mL clear, colourless, tubular glass vials fitted with 20 mm grey colour bromo butyl rubber stoppers and sealed with 20 mm aluminium seal with a red coloured PP disc.

Pack size:
1. Single vial packed in a printed carton with package insert.
2. 10 vials packed in a plain E-fluted box with partition and package insert

STORAGE INSTRUCTIONS:
Dry powder: Vials containing sterile **RAZOBIN** dry powder may be stored at controlled room temperature (at or below 25 °C). Keep the vial in the outer carton until required for use.
Solutions: Vials containing reconstituted solutions for intravenous use should be used immediately.
Chemical and physical in-use stability has been demonstrated for 24 hours at 25 °C and 48 hours at 2 —8 °C. **RAZOBIN** contains no preservatives, therefore reconstitution/dilution should take place in controlled and validated aseptic conditions.
RAZOBIN is for single use only. Any unused portion of the reconstituted/diluted solution must be discarded.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:
SOUTH AFRICA:
RAZOBIN 2: 44/20.1.1/0080
RAZOBIN 3: 44/20.1.1/0081
RAZOBIN 4: 44/20.1.1/0082
NAMIBIA:
RAZOBIN 2: 17/20.1.1/0039
RAZOBIN 3: 17/20.1.1/0040
RAZOBIN 4: 17/20.1.1/0041

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

AUROGEN
MEMBER OF THE AUROGENICS PHARMA GROUP

Aurogen South Africa (Pty) Ltd.
Woodhill Office Park, Building 1, First floor,
53 Phillip Engelbrecht Avenue,
Meyersdal, Ext. 12, 1448,
Johannesburg,
South Africa.

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:
Date of registration:
6 June 2014
Date of revision:
29 January 2024

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▼DETACH BEFORE DISPENSING

PATIENT INFORMATION LEAFLET

SOUTH AFRICA: S4

NAMIBIA: NS2

RAZOBIN 2 (Lyophilised powder for solution for injection/infusion)
RAZOBIN 3 (Lyophilised powder for solution for injection/infusion)
RAZOBIN 4 (Lyophilised powder for solution for injection/infusion)
Piperacillin sodium / Tazobactam sodium

Read all of this leaflet carefully before RAZOBIN is administered to you.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **RAZOBIN** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT RAZOBIN CONTAINS
The active substances are piperacillin sodium and tazobactam sodium.
RAZOBIN 2:
Each vial contains piperacillin sodium and tazobactam sodium cryodessicated powder for solution for injection/infusion equivalent to piperacillin 2,0 g and tazobactam 0,25 g.
Each vial contains 4,7 milli-equivalents (108 mg) of sodium.

RAZOBIN 3:
Each vial contains piperacillin sodium and tazobactam sodium cryodessicated powder for solution for injection/infusion equivalent to piperacillin 3,0 g and tazobactam 0,375 g.
Each vial contains 7,05 milli-equivalents (162 mg) of sodium.

RAZOBIN 4:
Each vial contains piperacillin sodium and tazobactam sodium cryodessicated powder for solution for injection/infusion equivalent to piperacillin 4,0 g and tazobactam 0,5 g.
Each vial contains 9,40 milli-equivalents (216 mg) of sodium.

2. WHAT RAZOBIN IS USED FOR
RAZOBIN injection contains two active ingredients, piperacillin, which is a penicillin-type antibiotic, and tazobactam, which is a medicine that prevents bacteria from inactivating piperacillin.
RAZOBIN is used to treat bacterial infections such as those affecting your chest, abdomen, skin and gynaecological infections.
RAZOBIN may also be used with medicines known as "aminoglycosides" to treat infections in patients who are unable to fight infections normally.
RAZOBIN is used to treat bacterial infections in children under 12 years of age with low white blood cell counts (neutropenia) and hence decreased ability to fight infection (used in combination with an aminoglycoside antibiotic for this purpose).
In hospitalised children aged 2 to 12 years, **RAZOBIN** is used to treat serious infections in the abdomen. **RAZOBIN** is not recommended to treat abdominal infections in children under 2 years.

3. BEFORE YOU RECEIVE RAZOBIN
You should not receive RAZOBIN:
- If you have ever had an unusual or allergic reaction to **RAZOBIN**, antibiotics known as penicillins or cephalosporins, or to medicines called beta-lactamase inhibitors.
- If you are pregnant or breastfeeding.

Take special care with RAZOBIN
Before receiving **RAZOBIN**:
- Tell your doctor if you are allergic to penicillins, cephalosporins, any other medications, or have a history of allergy. Stop taking **RAZOBIN** and get emergency help if you have any of these signs of a severe allergic reaction: difficulty breathing; swelling of your face, lips, tongue or throat.
- Tell your doctor if you develop diarrhoea either during or after taking **RAZOBIN**. If it becomes severe or persistent, or contains blood or mucus, you should tell your doctor immediately. This may be a sign of a serious side effect that affects the bowel. You may need urgent medical care.
- During long-term treatment, your doctor may want to take routine blood tests to monitor your kidney function, liver function and levels of blood cells.
- Tell your doctor immediately if you notice that you are bleeding or bruising more easily than normal.
- Tell your doctor if you develop symptoms of a new infection.
- If you receive doses that are higher than those recommended, you may experience seizures (convulsions).
- Tell your doctor if you are on a low sodium (salt) diet - **RAZOBIN** contains sodium.
- Tell your doctor if you have low levels of potassium in your blood or if you are taking diuretics (for heart problems or high blood pressure) or medicines for cancer. Your doctor might take a blood sample from time to time to test the levels of potassium in your blood.
- Tell your doctor if you have kidney problems, or if you receive haemodialysis treatment. Your doctor may check how well your kidneys are working before he gives you this medicine and adjust the dose to suit you.
- **RAZOBIN** may interfere with certain laboratory tests. Be sure your doctor and laboratory personnel know you are using **RAZOBIN**.
- **RAZOBIN** can cause interference in some tests for glucose in urine. Penicillins which are excreted in urine can cause a false-positive result. The doctor will request a test which is not affected by penicillins.

Haemophagocytic lymphohistiocytosis (haemophagocytic syndrome):
Haemophagocytic lymphohistiocytosis may occur. Tell your doctor if any abnormalities such as fever, swollen glands, feeling weak, feeling lightheaded, shortness of breath, bruising, or skin rash, are observed. Administration of **RAZOBIN** should be discontinued, and appropriate measures should be taken.

Pregnancy and Breastfeeding:
Tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding your baby.
- The safety of **RAZOBIN** during pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby while receiving **RAZOBIN**, please inform your doctor, pharmacist or other healthcare professional for advice before taking **RAZOBIN**.

Driving and using machinery:
There is no information to show that **RAZOBIN** affects the ability to drive a car or operate machinery.

Taking other medicines with RAZOBIN

Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines).

- Medicines for gout (probenecid).
- Tobramycin, an antibiotic.
- Aminoglycoside antibiotics.
- Preparations for thinning blood (e.g warfarin, heparin) —your doctor may want to monitor your blood clotting time more frequently if you are receiving anticoagulant treatment in combination with **RAZOBIN**.
- Methotrexate, used to treat cancer, rheumatoid arthritis and other inflammatory conditions —piperacillin may decrease the removal of methotrexate from the body, increasing the risk of its side effects. Your doctor may want to monitor the amount of methotrexate in your blood if you are receiving methotrexate treatment in combination with this medicine.
- Vercuronium, a muscle relaxant used in surgery.

If you are using any of these medicines, you may not be able to take **RAZOBIN**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side effects.

4. HOW TO RECEIVE RAZOBIN
- A doctor or nurse in hospital will give **RAZOBIN** to you. It will usually be given to you as a slow injection into a vein over 30 minutes.
- The usual adult and juvenile dose of **RAZOBIN** is 4/0,5 g given every 8 hours.
- Children with infections in or around the abdomen:
- The length of time you will be given **RAZOBIN** depends on the type and severity of your infection. It should be given for at least five days, and for 48 hours after all signs of illness and fever have gone.
- If you have kidney problems, your doctor may need to adjust the dose of **RAZOBIN** or how often it is given.

If you have the impression that the effect of **RAZOBIN** is too strong or too weak, talk to your doctor.

If you receive more RAZOBIN than you should:
Since a healthcare professional will administer **RAZOBIN**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.
Overdose symptoms may include nausea, vomiting, diarrhoea or seizures (convulsions).

If you missed a dose of RAZOBIN:
Your medication will usually be given to you by a healthcare professional. If you think you may have missed a dose, please tell your doctor or nurse.

5. POSSIBLE SIDE EFFECTS
RAZOBIN can have side effects.
Get emergency medical help if you have any of these signs of an allergic reaction:
- Hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have any of these serious side effects:
- Diarrhoea that is watery or bloody.
- Easy bruising or bleeding, nose bleeds.
- Widespread redness of the skin, or severe peeling of the skin.
- Seizures (convulsions).
- Fever, chills, sore throat, or other signs of infection.
- Anaemia (tiredness, being short of breath and looking pale).
- Inflammation of the wall of a vein with a blood clot forming in the affected segment of vein (pain in the part of the body affected, skin redness, swelling in the part of the body affected, warmth and tenderness over the vein).

Tell your doctor if you notice any of the following side effects and they worry you or if any of these symptoms are severe or do not go away:
- Thrush, headache, difficulty sleeping, muscle pain and weakness, hallucinations, dry mouth, pain, swelling, warmth or redness around the site of injection, flushing, nausea (queasiness, feeling that one is about to vomit), diarrhoea, vomiting, constipation, indigestion, inflammation of the mouth, abdominal pain, skin rash, eczema, itching, hives, joint pain, increased sweating, fever, tiredness, swelling due to retained fluid, increased heart rate.
- Unwanted effects of **RAZOBIN** that you may not be aware of whilst receiving your medicine include low blood pressure (seen as dizziness on standing), inflammation of the veins (swelling or redness along a vein which is extremely tender when touched), changes in the number of red or white blood cells or platelets, or the levels of potassium, glucose or protein in your blood, increases in levels of liver enzymes or bilirubin in the blood, changes in liver function (causing yellowing of the whites of your eyes or skin, itchy skin, darker urine and paler stools), changes in kidney function.

Not all side effects reported for **RAZOBIN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **RAZOBIN**, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF RAZOBIN
Dry powder: Vials containing sterile **RAZOBIN** dry powder may be stored at controlled room temperature (at or below 25 °C). Keep the vial in the outer carton until required for use.
Solutions: Vials containing the reconstituted solution should be used immediately or stored at 2 - 8 °C for not more than 24 hours.
Chemical and physical in-use stability has been demonstrated for 24 hours at 25 °C and 48 hours at 2 - 8 °C. **RAZOBIN** contains no preservatives therefore reconstitution/dilution should take place in controlled and validated aseptic conditions.
RAZOBIN is for single use only. Any unused portion of the reconstituted/diluted solution must be discarded (disposed of).
RAZOBIN is usually stored and handled by a healthcare provider. If you are using **RAZOBIN** at home, store **RAZOBIN** as directed by your pharmacist or healthcare provider.

Store all medicines out of the reach and sight of children.

7. PRESENTATION OF RAZOBIN
RAZOBIN 2:
30 mL clear, colourless, tubular glass vials fitted with 20 mm grey colour bromo butyl rubber stoppers and sealed with 20 mm violet coloured PP disc.
RAZOBIN 3:
30 mL clear, colourless, tubular glass vials fitted with 20 mm grey colour bromo butyl rubber stoppers and sealed with 20 mm light blue coloured PP disc.
RAZOBIN 4:
48 mL clear, colourless, tubular glass vials fitted with 20 mm grey colour bromo butyl rubber stoppers and sealed with 20 mm red coloured PP disc.

Pack size: 1. Single vial packed in a printed carton with package insert.
2. 10 vials packed in a plain E-fluted box with partition and package insert

8. IDENTIFICATION OF RAZOBIN
A white to off —white cryodessicated powder. When reconstituted, a light yellow coloured, clear solution free from visible particulate matter is formed.

9. REGISTRATION NUMBER/REFERENCE NUMBER
SOUTH AFRICA:
RAZOBIN 2: 44/20.1.1/0080
RAZOBIN 3: 44/20.1.1/0081
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NAMIBIA:
RAZOBIN 2: 17/20.1.1/0039
RAZOBIN 3: 17/20.1.1/0040
RAZOBIN 4: 17/20.1.1/0041

10. NAME AND ADDRESS OF REGISTRATION HOLDER
Aurogen South Africa (Pty) Ltd.
Woodhill Office Park, Building 1, First floor,
53 Phillip Engelbrecht Avenue,
Meyersdal, Ext. 12, 1448, Johannesburg,
South Africa.

11. DATE OF PUBLICATION
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